Family Medicine Clerkship Student Projects   Larner College of Medicine

2019

A Provider's Guide to Medical Cannabis: THC and CBD. Putting the Evidence to Work for Improved Patient Care

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PROBLEM IDENTIFICATION

- An estimated 50 million Americans or 20% of adults in the US have chronic pain. An additional 19.6 million Americans have high-impact chronic pain[11]
  - Chronic pain is reported at higher rates among adults who are women, older than 65 years of age, unemployed, living in poverty, insured with public health insurance, and residents of rural areas[11]

- According to the Anxiety and Depression Association of American, 40 million adults in the US, or 18%, suffer from anxiety. Anxiety disorders are the most common mental illness in the US[12]

- Problems with falling asleep or daytime sleepiness affect approximately 35 to 40% of the U.S. adult population annually and are a significant cause of morbidity and mortality[13]

- As of March 2018, there were 5,571 patients enrolled in the Vermont Marijuana Registry. Qualifying conditions include cancer, multiple sclerosis, positive status for human immunodeficiency virus, acquired immune deficiency syndrome, glaucoma, Crohn's disease, Parkinson's disease, and other conditions causing intractable symptoms.[14]

PROBLEM IDENTIFICATION CONTINUED

- In 2017, an ad hoc committee of the National Academies of Science, Engineering, and Medicine published the report *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research*. In the report, the committee presented nearly 100 conclusions related to the health effects of medical cannabis. Some of their conclusions include:
  - There is conclusive or substantial evidence that cannabis or cannabinoids are effective for the treatment of chronic pain in adults
  - There is moderate evidence that cannabis or cannabinoids are effective for improving short term sleep outcomes in individuals with sleep disturbance associated with sleep apnea syndrome, fibromyalgia, chronic pain, and multiple sclerosis
  - There is limited evidence that cannabis or cannabinoids are effective for improving anxiety symptoms and symptoms of PTSD.

DESCRIPTION OF NEED

- "I have patients ask me about medical marijuana and CBD all the time. I just don't know enough about it to feel really comfortable recommending it. It would be super helpful to have more information about potentially using medical cannabis as an alternative to less desirable medications for things like pain and insomnia" – Robert Luebbers, MD

- The number of opioid related fatalities has continued to rise with 33% of opioid related deaths in 2017 caused by prescription opiates.[15]

- 62% of Vermonters using medical cannabis have chronic pain.[16]

- 28.2% of Vermonters using medical cannabis have been diagnosed with an anxiety disorder.[16]

- 22.5% of Vermonters using medical cannabis have been diagnosed with insomnia or another sleep disorder.[16]

PUBLIC HEALTH COSTS

- The total cost of pain to society combining healthcare cost estimates and three productivity estimates ranges from $560 - $635 billion dollars annually.[17]

- Insufficient sleep costs $411 billion dollars annually, 2.28% of the United States GDP.[18]

- Federally, medical cannabis is considered a Schedule 1 substance. In Vermont, state legislature legalized the use of homegrown and medical cannabis. Because of this discrepancy, data on the public health costs of medical cannabis use is lacking.

Canada $21.4 billion — 1.35% GDP
United States $411 billion — 2.28% GDP
United Kingdom $50 billion — 1.86% GDP
Germany $60 billion — 1.56% GDP
Japan $138 billion — 2.92% GDP

Hafner et al. 2017

COMMUNITY PERSPECTIVE AND SUPPORT #1

- My first community interview took place with Ada Puches, the Community Outreach Coordinator for Champlain Valley Dispensaries and Southern Vermont Wellness. Ms. Puches provided me with a folder full of resources highlighting the scientific evidence behind the use of medical cannabis. She was extremely excited to learn about the project to help medical providers learn more about her field. She instructed me on the requirements for qualifying conditions for medical marijuana by Vermont State Law and educated me regarding the regulations faced by dispensaries in Vermont. She also helped me learn about the routes of administration of varying medical cannabis products and how the different products can be useful for different chief complaints.
  - "I love working in the field of medical cannabis because I have so much opportunity to help people. Most of my clients are using medical cannabis for pain, but a large portion of them use our products for help with sleep. Medical cannabis is so much safer than [for example] fentanyl patches and I'm glad that health care providers are interested in learning more.
    - -Ada Puches, Community Outreach Coordinator, Champlain Valley Dispensaries

COMMUNITY PERSPECTIVE AND SUPPORT #2

- My second community interview was with Paul Jerard, PA-C who runs the Vermont Cannabinoid Clinic providing medical guidance for medicinal cannabis. Mr. Jerard started working in the field of medical cannabis after speaking with some friends in Colorado who were doing similar advising. He realized that there was a need in Vermont for medical guidance and support for providers, so he started the Vermont Cannabinoid Clinic. Mr. Jerard was instrumental to my understanding of the pharmacology, adverse effects, and dosing suggestions for both THC and CBD products. He receives consults from other health care providers in order to help their patients manage their chronic conditions with medical cannabis. Most of his patients have several chronic conditions and are interested in exploring cannabis as an alternative therapy to more traditional allopathic medications.
    - "The type of cannabis that I usually suggest for most people is the cannabis with THC and CBD in a 1:1 ratio. CBD augments the psychoactive effects of THC and keeps people from feeling as high. You also get the anti-inflammatory effects from the CBD. It's important to start at a low dose and titrate up. Start with 2mg of THC and increase the dose by 0.5mg every 2-3 days until symptoms have improved
        - -Paul Jerard, PA-C, Vermont Cannabinoid Clinic

INTERVENTION AND METHODOLOGY

- I constructed an educational handout for medical providers discussing the scientific evidence behind the therapeutic effects of medical cannabis focusing on THC and CBD. The handout includes information on pharmacology, drug interactions, contraindications, adverse effects, routes of administration, and dosing recommendations for THC, CBD, and THC/CBD combinations. I also included information specific to ensuring that patients could purchase high quality CBD-rich oils from respected sources.

- A two question before handout survey was administered to 6 providers prior to their reviewing the handout. After the providers reviewed the handout, they completed an additional two question after handout survey to assess for the effectiveness of the handout.

- All 6 providers where medical doctors working at the UVMMC Family Medicine Clinic in South Burlington

- Before and after data were then plotted.

A Provider's Guide to Medical Cannabis: THC and CBD
Putting the Evidence to Work for Improved Patient Care

What is Medical Cannabis?

- Cannabis is a genus of flowering plants. It produces a resin containing several different cannabinoids
- Delta-9-tetrahydrocannabinol (or THC) is the main active cannabinoid in Cannabis
- Cannabidiol (CBD) is the main active cannabinoid in Hemp. Hemp is Cannabis with <0.3% THC concentration
- THC is responsible for the mood altering effects of cannabis
- THC is used by patients with pain, anxiety, insomnia, chemotherapy induced nausea, muscle spasticity, and reduced appetite
- CBD is used by patients with seizures, pain, inflammation, anxiety, insomnia, nausea, and IBD

Clinical Evidence: Why would you recommend medical cannabis for your patients?

In 2017, an ad hoc committee of the National Academies of Science, Engineering, and Medicine published the report *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research.* In the report, the committee presented nearly 100 conclusions related to the health effects of medical cannabis. Some of their conclusions include:

There is conclusive or substantial evidence that cannabis or cannabinoids are effective:
- For the treatment for **chronic pain** in adults (cannabis)
- Antiemetics in the treatment of **chemotherapy-induced nausea and vomiting** (oral cannabinoids)
- For improving patient-reported **multiple sclerosis spasticity symptoms** (oral cannabinoids)

There is moderate evidence that cannabis or cannabinoids are effective for:
- Improving short-term sleep outcomes in individuals with **sleep disturbance** associated with obstructive sleep apnea syndrome, fibromyalgia, chronic pain, and multiple sclerosis (cannabinoids, primarily nabiximols)

There is limited evidence that cannabis or cannabinoids are effective for:
- **Increasing appetite** and **decreasing weight loss associated with HIV/AIDS** (cannabis and oral cannabinoids)
- Improving clinician-measured multiple sclerosis spasticity symptoms (oral cannabinoids)
- Improving symptoms of **Tourette syndrome** (THC capsules)
- Improving **anxiety** symptoms, as assessed by a public speaking test, in individuals with **social anxiety disorders** (cannabidiol)
- Improving symptoms of **posttraumatic stress disorder** (nabilone; one single, small fair-quality trial)

Chronic Pain

- Evidence shows there is synergistic analgesia with greater-than-additive effects between cannabinoids and opioids[1]
- There is no enhancement of cardiorespiratory suppression with combination treatment[1,2]
- The treatment of chronic pain in this open-label, prospective cohort resulted in improved pain and functional outcomes, and a significant reduction in opioid use[9]
- Use of marijuana for chronic pain, neuropathic pain, and spasticity due to multiple sclerosis is supported by high-quality evidence[3]

Anxiety

- Existing preclinical evidence strongly supports CBD as a potential treatment for generalized anxiety disorder, panic disorder, social anxiety disorder, obsessive–compulsive disorder, and post-traumatic stress disorder when administered acutely[6]
- When co-administered with THC, CBD was able to attenuate the anxiogenic effect of high doses of THC. CBD was able to reduce post-stress anxiety in healthy subjects submitted to simulated public speaking[7]
- Cannabis consumption affects anxiety-related behaviors in a dose-dependent manner[6,7]

Sleep Disturbance

- In patients with unremitted PTSD, treatment with orally absorbable THC had beneficial effects on global symptom severity, sleep quality, frequency of nightmares, and PTSD hyperarousal symptoms[7]
- CBD may hold promise for REM sleep behavior disorder and excessive daytime sleepiness, while nabilone may reduce nightmares associated with PTSD and may improve sleep among patients with chronic pain[8]

THC   Cannabinoids   CBD

THC is a CYP450 inhibitor - 2C9 and 3A4.

FDA approved synthetic THC*
- Dronabinol— oral chemotherapy induced nausea/vomiting and weight loss in patients with HIV
- Nabilone— oral chemotherapy induced nausea/vomiting

Adverse Effects

THC: orthostatic hypotension, tachycardia, decreased intraocular pressure, nystagmus, conjunctival injection, lethargy, decreased concentration, psychomotor impairment, euphoria, acute panic or paranoid reaction, altered motivation, increased appetite, tolerance

Vermont Medical Cannabis Dispensaries

Champlain Valley Dispensary— Burlington, South Burlington
Southern Vermont Wellness— Brattleboro, Middlebury
Grassroots Vermont—Brandon
PhytoCare Vermont—Bennington

> Start with 2mg of THC. Increase by 0.5mg every 2 days until symptom relief is achieved.
> -Paul Jerard, PA-C.
> Vermont Cannabinoid Clinic

Dosing Recommendations: THC

Chronic Pain: 2mg—10mg
Sleep Disturbance: 2mg—5mg
Anxiety: 2mg—25mg
MS Spasticity: 2mg—5mg
Anti-emetic: 2mg—25mg

Pharmacology

- Cannabinoids binds to CB1 receptors in the CNS and CB2 receptors, mostly expressed in cells of the immune system, with varying affinity.
- THC is a stronger agonist than CBD.
- Clinically significant drug-drug interactions due to CYP450 inhibition by medical cannabis have not been reported.
- *Synthetic cannabinoids are associated with more morbidity and mortality than phytocannabinoids (naturally occurring cannabinoids)

Relative Contraindications to Medical Cannabis

- Pregnant or breast feeding mothers—possible link between smoking cannabis during pregnancy and low birth weight
- Adolescents— heavy users show disadvantages attention, learning, and processing speed. Resolves within 3 months of abstinence
- Children—possibility for severe disorientation, confusion, and anxiety. Long term studies have not been done
- Cannabis Hyperemesis Syndrome

Routes of Administration

- **Smoking**—fastest onset < 5 mins, duration 2-3 hours
- **Vaping**—onset < 5 mins, duration 2-3 hours
- **Concentrates**—wax, shatter, distillate. Most potent products with the highest levels of cannabinoids. Used in smoking or vaping or creation of infused products
- **Edibles/Capsules**—longest onset 60-90 minutes, duration 6-8 hours
- **Tinctures**—most accurate dosing method, onset 15-30 minutes sublingually or 60-90 minutes when ingested, duration 4-6 hours
- **Transdermal Patches/Gel Pens**—quick onset, long duration of effect
- **Creams/Ointments**—regional pain relief, onset 30 minutes, duration 2-4 hours

Dosing Recommendations: THC/CBD combo*

For the cannabinoid naïve patients, START LOW and suggest 1:1 products of THC:CBD

Chronic Pain: 2mg/10mg—10mg/25mg
Sleep Disturbance: 2mg/10mg—5mg/40mg
Anxiety: 2mg/10mg—10mg/25mg
MS Spasticity: 2mg/20mg—5mg/50mg

*The combination of THC and CBD increases clinical efficacy while reducing adverse events[4]

CBD is a CYP450 inhibitor—2C19 and 3A4

CBD is a weak partial agonist and can antagonize the effect of THC at CB receptors

FDA approved synthetic CBD*
- Epidiolex—oral. Seizures associated with Lennox-Gastaut Syndrome or Dravet Syndrome in patients 2 years of age or older

Adverse Effects

CBD: fatigue, diarrhea, weight change[10]

Ensuring Your CBD is Good Quality

- Choose CBD products made with American grown hemp (VT, CO, OR, WA, KY, TN)
- Choose "full spectrum" CBD-rich hemp extracts
- Look for labels that indicate the amount of THC/CBD per serving, not whole bottle
- Beware of companies that make explicit health claims—this is illegal
- Seek out CBD-rich products derived from high-resin cannabis grown sustainably
- Avoid vape cartridge products with thinning agents— propylene glycol and ethylene glycol
- Beware companies claiming to source CBD from seed or stalk

Dosing Recommendations: CBD

Chronic Pain: 10mg—25mg
Sleep Disturbance: 10mg—40mg
Anxiety: 10—25mg
MS Spasticity: 20mg—50mg
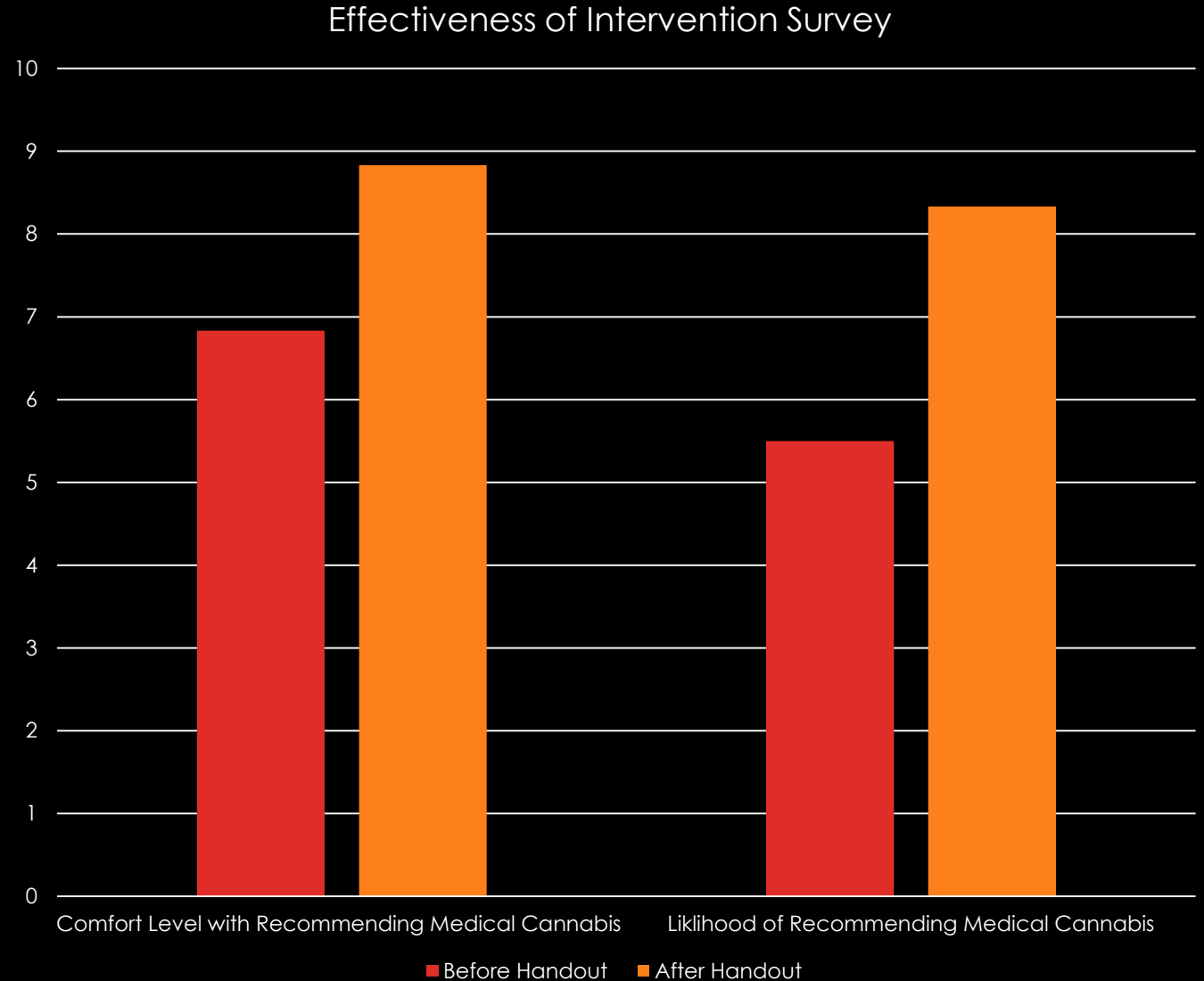**IBD**: 200-300mg BID

Resources for Providers:

-Vermont Cannabinoid Clinic: Medical Guidance for Medicinal Cannabis

     Paul Jerard, PA—C   pbj@vtcclinic.com

-Ada Puches, Community Outreach Coordinator

     Champlain Valley Dispensary and Southern Vermont Wellness

     ada@cvdvt.org

-Vermont Marijuana Registry— http://medicalmarijuana.vermont.gov

-Project CBD— projectCBD.org

     California-based nonprofit dedicated to promoting and publicizing research into the medical uses of

     cannabidiol (CBD)

-The University of Vermont's Free Cannabis Speakers Series—

     learn.uvm.edu/com/program/cannabis-speaker-series-from-botany-to-medicine/

-The Society of Cannabis Clinicians—cannabisclinicians.org

-United Patient's Group—unitedpatientsgroup.com

-Healer.com

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RESULTS AND PROVIDER RESPONSE

- Response to the handout was positive!

- Comfort level with recommending medical cannabis increased by 2 points after providers reviewed the handout

- Likelihood of recommending medical cannabis increased by 1.8 points after providers reviewed the handout

- 100% of providers said they would use the information from the handout in their future practice

Effectiveness of Intervention Survey

Bar chart with y-axis from 0 to 10. Categories: "Comfort Level with Recommending Medical Cannabis" and "Liklihood of Recommending Medical Cannabis". Legend: Before Handout (red), After Handout (orange).

Evaluation of Intervention Effectiveness

Medical Cannabis Handout

<u>Before Handout:</u>

Please rate your comfort level with recommending medical cannabis (THC or CBD or THC/CBD combo) to your patients for qualifying or indicated conditions.

Very Uncomfortable				Somewhat Comfortable				Very Comfortable		
0	1	2	3	4	5	6	7	8	9	10

Please rate how likely you were to recommend medical cannabis (THC or CBD or THC/CBD combo) to your patients for qualifying or indicated conditions.

Very Likely				Somewhat Likely				Very Likely		
0	1	2	3	4	5	6	7	8	9	10

<u>After Handout:</u>

Please rate your comfort level with recommending medical cannabis (THC or CBD or THC/CBD combo) to your patients for qualifying or indicated conditions.

Very Uncomfortable				Somewhat Comfortable				Very Comfortable		
0	1	2	3	4	5	6	7	8	9	10

Please rate how likely you were to recommend medical cannabis (THC or CBD or THC/CBD combo) to your patients for qualifying or indicated conditions.

Very Likely				Somewhat Likely				Very Likely		
0	1	2	3	4	5	6	7	8	9	10

Will you use information from this handout in your clinical practice in the future? Circle One

Yes   Maybe   No

EVALUATION OF EFFECTIVENESS AND LIMITATIONS

- Based on my preliminary results, I can conclude that my handout was effective at increasing provider confidence and liklihood in recommending medical cannabis as therapeutic intervention for evidence based indications.

- Anecdotally, many providers in Vermont would like to find an effective alternative to prescribing medications like opiates and benzodiazepines for chronic pain and anxiety, respectively. I can conclude that my intervention was effective at increasing provider knowledge base given the 100% provider response that they will use the information in their future practice.

- My current sample size for evaluation of effectiveness is small. Increasing the sample size would increase the power of the study and increase confidence in the effectiveness of the handout.

- Limitations:
  - Small sample size – 6 providers were surveyed
  - Current legislation and regulations do not provide adequate assurance that THC or CBD products contain what is advertised on the label. Quality control is currently regulated by the state for medical marijuana and is not regulated at all for CBD. Providers have to ensure that patients are aware of the possibility of failed drug testing while using medical cannabis products.
  - There was not enough time during the 6 week family medicine clerkship to evaluate the future implications of increased provider education on this topic.

RECOMMENDATIONS FOR FUTURE INTERVENTIONS AND PROJECTS

- Increase distribution of the hand out among family medicine providers in the UVM Health Network

- Distribute the handout to other providers not associated with Family Medicine. Providers in every field of medicine will care for patient with chronic pain, anxiety, sleep issues, etc.

- Future medical students can track the number of times that providers recommend medical cannabis to their patients for conditions backed by scientific evidence. If the number of recommendations increases, it is likely that this is secondary to increased knowledge gained from the handout.

- The field of medical cannabis is a burgeoning field of research with new evidence published daily. A future medical student could update the handout based on the most up to date information annually following publishing of new high quality evidence.

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CONSENT FOR INTERVIEWS

- Thank you for agreeing to be interviewed. This project is a requirement for the Family Medicine clerkship. It will be stored on the Dana Library ScholarWorks website. Your name will be attached to your interview and you may be cited directly or indirectly in subsequent unpublished or published work. The interviewer affirms that he/she has explained the nature and purpose of this project. The interviewee affirms that he/she has consented to this interview. Yes __x___ / No _____ If not consenting as above: please add the interviewee names here for the department of Family Medicine information only. Name: __Ada Puches, Community Outreach Coordinator, Champlain Valley Dispensary
  - Name: Paul Jerard, PA-C, Vermont Cannabinoid Clinic